Citation:

Hession M, Rolland C, Kulkarni U, Wise A, Broom J. Systematic review of randomized controlled trials of low-carbohydrate vs. low-fat/low-calorie diets in the management of obesity and its comorbidities. Obes Rev. 2009 Jan;10(1):36-50.

PubMed ID: 18700873

Study Design:

Systematic Review

Class:

M - <u>Click here</u> for explanation of classification scheme.

Research Design and Implementation Rating:



POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

This systematic review focuses on randomized controlled trials of low-carbohydrate diets compared with low-fat/low-calorie diets.

Inclusion Criteria:

The protocol used for this systemic review follows the methods recommended by the Cochrane Collaboration. RCTs included:

- assessed the weight-loss effects of LC/HP (low fat/high protein) diets against LF/HC diets (low fat/high carbohydrate).
- conducted between January 2000 to March 2007
- adult population; minimum age of 18 years
- participants had a mean or median body mass index (BMI) of \geq 28 kg/m²
- were at least 6-month duration

Exclusion Criteria:

Summary of reasons for which papers were not included in this systematic review:

- Not a randomized controlled trial
- Study was less than 6-month duration
- Mean/median body mass index of subjects was less than 28 kg/m²
- Carbohydrate content of the "low carbohydrate" diet was too high
- Subjects did not receive an appropriate treatment
- Subjects were not human
- Subjects were under 18

Description of Study Protocol:

Recruitment

- Thirteen electronic databases were searched including MEDLINE, Commonwealth Agricultural Bureau (CAB) abstracts and the Cochrane Central Register of Controlled Trials.
- The search strategy incorporated weight loss, cardiovascular disease and obesity-related terms and text terms specific to each database.
- Seven obesity and nutrition journals were hand searched including the International Journal of Obesity and Obesity Research.

Design: Systematic review

Blinding used (if applicable): not applicable

Intervention (if applicable):

The types of dietary intervention evaluated were:

- HP "ketogenic" diet, where the carbohydrate content < 40 g/d, irrespective of calorie content
- LC diets (carbohydrate $\leq 60 \text{ g/d}$)
- "Healthy eating" advice
- LF (30% of less daily energy from dietary fat) 600 kcal deficit diet

Statistical Analysis

- A data abstraction form was created for this review based on a standard form.
- For each study, data were abstracted and checked by different researchers prior to electronic data entry.
- The computer program Review Manager 4.2.2 was used for the analysis of the data from the reviews. If results from studies could be quantitatively combined, a statistical meta-analysis of the data was undertaken to determine the typical effect size of the intervention.
- For continuous data, a weighted mean difference (WMD) was calculated.
- The chi-square test was used to test for heterogeneity across the studies. The significance value was set at 0.05.

Data Collection Summary:

Timing of Measurements: not applicable

Dependent Variables

Weight loss or prevention of weight gain was the main outcomes assessed from the RCTs. With regard to cardiovascular disease risk factors, the following outcomes were also included:

- Serum lipids, including total cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol and triacylglycerols
- Systolic and diastolic blood pressure
- Glycemic control

Independent Variables

- HP "ketogenic" diet, where the carbohydrate content < 40 g/d, irrespective of calorie content
- LC diets (carbohydrate $\leq 60 \text{ g/d}$)
- "Healthy eating" advice
- LF (30% of less daily energy from dietary fat) 600 kcal deficit diet

Control Variables

Description of Actual Data Sample:

Initial N: A total of 13 out of 123 articles met the inclusion criteria and were included in this systematic review.

- Brehm et al., 2002
- Brinkworth et al., 2004
- Cardillo et al., 2006
- Dansinger et al., 2005
- Due et al., 2004
- Foster et al., 2003
- Gardner et al., 2007
- Samaha et al., 2003
- Seshadri et al., 2004
- Stern et al., 2004
- Truby et al., 2006
- Tsai et al., 2004
- Yancy et al., 2004

Attrition (final N): as above

Age: not applicable

Ethnicity: not applicable

Other relevant demographics

Anthropometrics

Location: international studies

Summary of Results:

Key Findings:

- There were significant differences between the groups for weight, high-density lipoprotein cholesterol, triacylglycerols and systolic blood pressure favoring the low-carbohydrate diet.
- There was a higher attrition rate in the low-fat as compared with the low-carbohydrate groups suggesting a patient preference for a low-carbohydrate/high protein approach.
- Evidence from this systematic review demonstrates that low-carbohydrate/high-protein diets are more effective at 6 months and are as effective, if not more, as low-fat diets in reducing weight and cardiovascular disease risk up to one year.

Author Conclusion:

It is not known with certainty which aspect of LC diets causes the weight loss and the cardiovascular disease risk factor changes. Whether it is the LC, the HP or calorie restriction needs to be examined. In addition, there is a need to assess if the greater weight loss achieved at 6 months on a LC/HP diet results in more important long-term improvements in cardiovascular disease.

Reviewer Comments:

Authors note the following limitations:

- High attrition rates lead to smaller statistical power
- Use of a RCT design may not be appropriate
- Evidence of heterogeneity between the studies included in the analysis

Research Design and Implementation Criteria Checklist: Review Articles

Relevance	e Questions	
1.	Will the answer if true, have a direct bearing on the health of patients?	Yes
2.	Is the outcome or topic something that patients/clients/population groups would care about?	Yes
3.	Is the problem addressed in the review one that is relevant to nutrition or dietetics practice?	Yes
4.	Will the information, if true, require a change in practice?	Yes
Validity (Questions	
1.	Was the question for the review clearly focused and appropriate?	Yes
2.	Was the search strategy used to locate relevant studies comprehensive? Were the databases searched and the search termsused described?	Yes
3.	Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?	Yes
4.	Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible?	Yes
5.	Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined?	Yes
6.	Was the outcome of interest clearly indicated? Were other potential harms and benefits considered?	Yes

7.	Were processes for data abstraction, synthesis, and analysis described? Were they applied consistently across studies and groups? Was there appropriate use of qualitative and/or quantitative synthesis? Was variation in findings among studies analyzed? Were heterogeneity issued considered? If data from studies were aggregated for meta-analysis, was the procedure described?	Yes
8.	Are the results clearly presented in narrative and/or quantitative terms? If summary statistics are used, are levels of significance and/or confidence intervals included?	Yes
9.	Are conclusions supported by results with biases and limitations taken into consideration? Are limitations of the review identified and discussed?	Yes
10.	Was bias due to the review's funding or sponsorship unlikely?	Yes

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